Docket No. 4007561-173520 **PATENT**

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/Holly D. Kozlowski/

Holly D. Kozlowski

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Kazuyuki Yamane et al	:	Confirmation No.:	8257
Serial No.:	10/529,449	:	Group Art Unit:	1796
Filing Date:	March 28, 2005	:	Examiner:	Toscano, Alicia

For: **High-Molecular Weight Aliphatic Polyester and Production Process Thereof**

SECOND DECLARATION UNDER 37 C.F.R. 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

KAZUYUKI YAMANE declares as follows:

1. He is a co-inventor of and is familiar with the present U.S. Patent Application Serial No. 10/529,449. He has a Master of Engineering in polymer engineering from the Graduate School of Nagoya Institute of Technology, Nagoya, Japan, he has been employed by the Assignee, Kureha Corporation, since April 1991, where he has conducted research and development in the field of polymer science, including polyglycolic acid and processes, in the Research Center of Kureha Corporation, he is a coinventor of eight U.S. Patents issued from 2004 to the present date relating to polyglycolic acid and/or processes as set forth in the attached USPTO Patent database search results, and he is a coinventor of a number of pending U.S. Applications relating to polyglycolic acid and/or processes as set forth in the attached USPTO Publication database search results.

2. He is familiar with the Matsumoto Japanese (JP) Patent Application Laid-Open No. 2001-323056 (Matsumoto) cited in the present application and the position asserted by the Examiner that the process of Matsumoto and the process defined by present claim 11 are similar and the differences would have been obvious to one skilled in the art.

3. Based on his extensive experience in the research and development of polyglycolic acid and processes relating to production of polyglycolic acid, it is his opinion that the process of claim 11 has important differences over the process of Matsumoto, and that the differences would not have been obvious. The basis of his opinion includes the following:

a. In contrast to the chain-lengthening reaction which is conducted in the process of claim 11, Matsumoto teaches a method for capping the terminal carboxyl groups of an aliphatic polyester resin with an oxazoline or oxazine compound. Those of ordinary skill in the polymer art, including the Matsumoto inventors, are familiar with end capping reactions and chain lengthening reactions and recognize they are distinct and different reactions. Those of ordinary skill in the polymer art appreciate that an end capping reaction does not significantly change the polymer chain length or consequently the molecular weight of a polymer, or other properties related to chain length and molecular weight, for example melt viscosity. Those of ordinary skill in the polymer art also appreciate that a chain lengthening reaction will significantly change the polymer chain length and consequently the molecular weight of a polymer, along with other properties related to chain length and molecular weight, for example melt viscosity. From the teachings of Matsumoto, it is apparent to one of ordinary skill in the polymer art that the Matsumoto end capping reaction is not a chain lengthening reaction according to the process of claim 11.

b. In the process of claim 11, the chain lengthening reaction is conducted by melt kneading at a reaction temperature not lower than the melting temperature of the ring-opening polymer, but not higher than 240°C, and a reaction time of 10 to 30 minutes. Matsumoto does not teach these process requirements. Matsumoto teaches in Example 3 heating a polyglycolic acid having a melting point of 224°C in a twin-screw kneading extruder having a cylinder temperature of 270°C. Matsumoto does not indicate a process time. One of ordinary skill in the art will recognize that in the twin-screw kneading extruder used in Matsumoto, the degree of kneading is high so a short process time would typically be required.

c. One of ordinary skill in the art of polymer processing will appreciate that both reaction temperature and reaction time can significantly effect melt kneading reactions of resins. For example, when melt-kneading at a high temperature as in Matsumoto, it is my opinion that the mobility of a polyglycolic acid molecule becomes extremely high and molecular motion is activated. An end-capping reaction wherein the oxazoline compound reacts to the terminal of polyglycolic acid would be considered to take place preferentially because the twin-screw kneading extruder employs a high degree of kneading. On the other hand, in the process of present claim 11, the melt-kneading is conducted at a temperature which is at least 30°C lower than that of Matsumoto, and it is my opinion that the mobility of the polyglycolic acid molecule and the molecular motion are low as compared with those of Matsumoto. A primary reaction between the terminal of polyglycolic acid and a first oxazoline group of the oxazoline compound would be considered to first take place in a region where the molecular motion is restricted, whereafter an unreacted oxazoline group of the compound reacts with another polyglycolic acid because the reaction is conducted for a relatively long period of time, i.e., 10-30 minutes,

resulting in chain lengthening. Thus, a difference of 30°C in reaction temperature, especially using a reaction time of 10-30 minutes as in the process of claim 11, is a significant distinction over the process of Matsumoto.

4. The Assignee, Kureha Corporation, is completing the manufacture of a $100 million manufacturing plant in West Virginia for the production of polyglycolic acid (PGA) polymer. As set forth in the attached PR Newswire Publication from December 2007 announcing the project, for many years there has been no high volume, cost effective manufacturing process available for PGA, and therefore its production has been limited to relatively small-scale operations. Kureha is the first and only company which succeeded in developing technology to produce large volumes of PGA. This demonstrates the importance of a process as in claim 11 for the production of polyglycolic acid and that small improvements can be significant on a large manufacturing scale.

5. He hereby declares that all statements made herein of his own knowledge are true and that all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, Section 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Kazuyuki Yamane

KAZUYUKI YAMANE

Date: Aug. 5th, 2010

USPTO Patent Full-Text and Image Database

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Results of Search in US Patent Collection db for:
IN/Yamane-Kazuyuki: 8 patents.
*Hits **1** through **8** out of **8***

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Refine Search in/Yamane-Kazuyuki

PAT. NO.		Title
1	7,235,673	T Glycolide production process, and glycolic acid oligomer for glycolide production
2	7,179,868	T Polyglycolic acid-based resin composition and shaped product thereof
3	7,067,611	T Polyhydroxycarboxylic acid and its production process
4	6,951,956	T Crystalline polyglycolic acid, polyglycolic acid composition and production process thereof
5	6,916,939	T Process for the preparation of cyclic esters and method for purification of the same
6	6,891,048	T Glycolide production process, and glycolic acid composition
7	6,852,827	T Polyester production process and reactor apparatus
8	6,693,204	T Method for purification of cyclic ester

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PATENT APPLICATION FULL TEXT AND IMAGE DATABASE

Searching AppFT Database...

Results of Search in AppFT Database for:
in/Yamane-Kazuyuki: 31 applications.
*Hits **1** through **31** out of **31***

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Refine Search in/Yamane-Kazuyuki

	PUB. APP. NO.	Title
1	20100184891	LOW MELT VISCOSITY POLYGLYCOLIC ACID, PRODUCTION PROCESS THEREOF, AND USE OF LOW MELT VISCOSITY POLYGLYCOLIC ACID
2	20100168446	METHOD FOR PURIFICATION OF CYCLIC ESTER
3	20100148391	Filament of polyglycolic acid resin and process for producing the same
4	20100093948	AROMATIC POLYESTER RESIN MOLDINGS AND PROCESS FOR PRODUCTION THEREOF
5	20100087589	AROMATIC POLYESTER RESIN COMPOSITION
6	20100063219	AROMATIC POLYESTER RESIN COMPOSITION AND PROCESS FOR PRODUCTION THEREOF
7	20090298979	Method for Controlling Water Resistance of Polyglycolid Acid Resin
8	20090275692	Alphatic polyester composition and method for producing the same
9	20090081396	Polyglycolic Acid Resin-Based Layered Sheet and Method of Producing the Same
10	20090030094	Bottle excellent in recyclability and method for recycling the bottle
11	20080167409	Aliphatic Polyester Resin Composition
12	20080107847	Multilayered Polyglycolic-Acid-Resin Sheet
13	20080069988	Multilayer Sheet Made of Polyglycolic Acid Resin
14	20070244293	Process for Producing Aliphatic Polyester Reduced in Residual Cyclic Ester Content
15	20070150001	Filament of polyglycolic acid resin and process for producing the same
16	20070095957	Method of recycling laminated molding
17	20070057395	Process for producing thermoplastic resin molding
18	20060255495	Method for producing multilayer stretch-molded article
19	20060100392	Polyglycolic acid-based resin composition and shaped product thereof
20	20060047088	High-molecular aliphatic polyester and process for producing the same
21	20050221032	Container of biodegradable heat-resistant hard resin molding

22	20050175801	Bottle excellent in recyclability and method for recycling the bottle
23	20050106346	Method of heat-treating packaged product and heat-treated packaged product
24	20040230026	Polyester production process and reactor apparatus
25	20040192881	Polyhydroxycarboxylic acid and its production process
26	20040122240	Glycolide production process, and glycolic acid oligomer for glycolide production
27	20040087805	Glycolide production process, and glycolic acid composition
28	20030191326	Process for the preparation of cyclic esters and method for purification of the same
29	20030125508	Crystalline polyglycolic acid, polyglycolic acid composition and production process thereof
30	20030125431	Crystalline polyglycolic acid, polyglycolic acid composition and production process thereof
31	20030109722	Method for purification of cyclic ester

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Kureha Corporation to Launch New Polyglycolic Acid (PGA) Business in West Virginia

TOKYO, Dec. 18 /PRNewswire/ -- Kureha Corporation today announced it will invest more than $100 million in a new, wholly-owned subsidiary to build a plant for the production and sale of the high performance polymer, polyglycolic acid (PGA). The production facility will be located on the Ohio River site in Belle, W.Va.

According to Dr. Tokio Iwasaki, president and chief executive officer of Kureha Corporation, construction of the plant is scheduled to start in early 2008, with polymer production to begin in early 2010. The first phase of the construction will be a semi-works facility that will create approximately 60 new jobs and result in a turnover of greater than $100 million.

Kureha Corporation is a leading global supplier of specialty chemicals and plastics, targeting diverse markets such as consumer packaging, household products, pharmaceuticals, agriculture and other industrial applications. The company continues to focus on growth and diversification by leveraging its investment in research and development and the Kureha mission of the pursuit of excellence.

"The establishment of this PGA business is another milestone in Kureha's vision of becoming a specialty products company, radically reshaping the way we approach our markets and customers," said Iwasaki. "With the development of this breakthrough technology and the strong intellectual property surrounding our work, PGA will become a centerpiece in the company's strategy of focusing on value-added, highly differentiated polymers, setting us on a path of strong growth and profitability."

PGA is a polyester resin, which offers high gas barrier to both CO2 and O2, considerable hydrolysis and excellent mechanical strength. The unique combination of properties makes PGA usually suited for high performance packaging and industrial applications. Today, the targeted application for PGA is multi-layer polyethylene terephthalate (PET) bottles for carbonated soft drinks and beer. Where PGA offers a gas barrier 100 times higher than that of PET, it is possible to reduce the amount of PET used in these bottles by more than 40 percent, while maintaining the equivalent barrier against the gases. This bottle redesign has the potential of yielding cost reduction as well as source reduction opportunities in the marketplace.

Perhaps most importantly, PGA's unique hydrolytic properties make it highly compatible with widely practiced industrial PET recycling processes, ensuring the material does not interfere with the purity and quality of recycled PET. In another packaging application, PGA multi-layer designs have been proven to enhance the gas and moisture barrier of bio-based polymers such as polylactic acid (PLA). Through expanded use in biodegradable applications, PGA will further contribute to environmental conservation.

In addition, Kureha is working with several development partners to commercialize industrial applications that utilize the easily controllable hydrolysis rate and excellent mechanical strength of PGA.

"PGA distinctly fits in the sweet spot of Kureha's focus on the triple bottom line: economic, environmental and social responsibility," said Mr. Iwasaki. "Our aim is to maximize value while remaining committed to environmental and compliance issues, and to society, contribute to the local community as a responsible corporate citizen. When considering the potential unique and diverse opportunities for PGA, we estimate the business could eventually achieve a turnover in excess of $1 billion."

West Virginia Gov. Joe Manchin said Kureha could not have selected a better site than the Belle plant. "I am elated that Kureha has selected West Virginia for its newest manufacturing location, and proud that such a technology leader will be found in the Mountain State," Manchin said. "This new phenomenon of Kureha Corp., DuPont and West Virginia proves that we can compete in the global chemical manufacturing marketplace."

"U.S. Gov. Joe Manchin said he is thrilled Kureha has become the 20th Japanese company to invest in West Virginia. "Our state has seen so much growth and success with Japanese companies in recent years, and I have no doubt that with this innovative product being made in Belle, that growth will only continue," he said. "It is time you see an important announcement like that one Kureha made today, what you're really seeing are more young investments in our state's economy, more jobs for West Virginians, and further validation that West Virginia is a powerful competitor in the global marketplace."

"We believe the new Kureha plant is a great synergistic fit with our operations here at Belle," said DuPont Belle Plant Manager Bill Meade. "It also will support our infrastructure at the site to make all of our businesses more competitive."

Tweedie said PGA's simple molecular structure and rare combination of properties suggest that, from a scientific viewpoint, there is a low probability of finding a polymer in the future that rivals PGA's unique value proposition.

For many years there has been no high volume, cost effective manufacturing process available for PGA, and therefore its production has been limited to relatively small-scale operations for the manufacture of surgical sutures. Kureha is the first and only company, which succeeded in developing technology to produce large volumes of PGA, supporting this development with significant intellectual property. In 2002, a 1,000-ton plant was built at Kureha's Iwaki Factory in Japan, and from then on Kureha has been vigorously developing applications suitable for PGA.

SOURCE Kureha Corporation

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